NMPA

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

????????

???????????? ?21?

□□□

??? ??????????

□□□

□□□

□□□□□
□□□□□

□□□□□
□□□□□

□□□

??????????????????

????

□□□

□□□

??????????????????

????

□□□

□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□ GCP
□□□□□□□□□□□□□□□□□□□

□□□

□□□

??????????????????

????

□□□

□□□

□□□

□ 2□□□□□□□□□□□□□□□□□□

□ 3□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□

2. ???????

□□□□□□□□□□□□□□□□□□□

4. ?????????

□□□

??????????????????

???????

□□□□□□□□□□□ locally applied, locally acting products□ LALAP □□□□□□□□□□□□

??????????????

1. ???

□□□

□□□□□□□□□□□□□□□

□□□□□□□□□□□□□□□

□□□

□□□

5. ?????

□□□

use in the treatment of asthma in children and adolescents,2009.

7. FDA Guidance on Topical Dermatologic Corticosteroids: in vivo bioequivalence, 1995.

??????????????????????????????

????

?????

□□□

□□□

□□□

□□□

□□□

□□□

□□□

□□□

“

-

????????

????

[1] ICH. E1: The extent of Population Exposure to Assess Clinical Safety for Drugs Intended for Long-term Treatment of Non- life-threatening Conditions [EB/OL]. Oct 1994. https://www.cde.org.cn/ichWeb/guideIch/toGuideIch/3/0

[2] ICH. E5(R1): Ethnic Factors in the Acceptability of Foreign Clinical Data [EB/OL]. Feb 1998.

[3] ICH. E8(R1): General Considerations for Clinical Trials [EB/OL]. Oct 2021.

[4] ICH. E9: Statistical Principles for Clinical Trials [EB/OL]. Feb 1998. https://www.cde.org.cn/ichWeb/guideIch/toGuideIch/3/0

[5] ICH. E10: Choice of Control Group and Related Issuesin Clinical Trials [EB/OL]. July 2000.https://www.cde.org.cn/ichWeb/guideIch/toGuideIch/3/0

[6] ICH. E17: General principle on planning and Designing Multi-Regional Clinical Trials [EB/OL]. Nov 2017. https://www.cde.org.cn/ichWeb/guideIch/toGuideIch/3/0

[7] ICH. E19□ A Selective Approach To Safety Data Collection In Specific Late-Stage Pre-approval Or Post-Approval Clinical Trials [EB/OL]. Sep 2022. https://www.cde.org.cn/ichWeb/guideIch/toGuideIch/3/0

[8] □□□□□□□□□ . □□□□□□□□□□□□□□□□□□ [EB/OL] 2017□ 1□ . https://www.cde.org.cn/zdyz/domesticinfopage?zdyzIdCODE=b32eaabf2c4cc56570c23c19f9608076

[9] □□□□□□□□□ . □□□□□□□□□□□□□□□□□□

??????????????????????????
??????????????????

????

□□□□□□□□□□ TDS
□□□□□□□□□□

□□□□□□□□□□□□ TDS □□□□□□□□□□□□□□□□□□□□□□□□ TDS □□□□□□□□□□□□□□□□□□□□

3	>0% <50%	□□□□□ TDS □□□□□□
4	0%	TDS □□□□□□

□□□□ 80
□□□□□

??????????????

□□□□□□□□□□ I/S□□ TDS □□□□□□□□□□□

4. □□□□

TDS □□□□

□□□□□□ 1 □□□□□ “□□□□□ ”□□□□□□

□□□□□□□ TDS□□□ 48□ 72□□□□□□□□ ≥ 2 □□□ TDS □□□□□□□□□

[2] FDA. Assessing the Irritation and Sensitization Potential of Generic Transdermal and Topical Delivery Systems for ANDAs Draft Guidance for Industry [EB/OL]. Apr 2023. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-irritation-and-sensitization-potential-transdermal-and-topical-delivery-systems-andas.

[3] EMA. Guideline on the pharmacokinetic and clinical evaluation of modified release 279 dosage forms [EB/OL]. Nov 2014. https://www.ema.europa.eu/en/pharmacokinetic-clinical-evaluation-modified-release-dosage-forms-scientific-guideline

[4] □□□□□□□□□□□□□□□□ .□□□□□□□□□□□□□□□□□□□□□□□□ [EB/OL]. 2022 □ 5 □ .

[5] □□□□□□□□□□□□□□□□ .□□□□□□□□□□□□□□□□ IVRT□□□□□□□ IVPT □□□□□□□□□□ [EB/OL]. 2025 □ 6 □ .

[6] FDA. Assessment of Adhesion for Topical and Transdermal Systems Submitted in New Drug Applications [EB/OL]. Jul 2021. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessment-adhesion-topical-and-transdermal-systems-submitted-new-drug-applications.

??????????????????????

????

□□□

□□□

□□□

□□□

□□□□	□□□□	□□
□□□□□□□	Cell and Gene Therapy (CGT)	□□□□□□□

??????????????????????????

????

□□□□□□□ single arm trial□ SAT □□□□□□□□

□□□□□ SAT□□□□□□□□□□□□□□□□□□□□ SAT
□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□ /□□□□□□□□□□□□□□ SAT
□□□□□□□□□□□□□□□□□□□

??????????????????????

□□□

□□ A□□□ B□□□

□□□

13 6□□□